

## § 870.4075

determine the size of the appropriate replacement heart valve.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38797, July 25, 2001]

### Subpart E—Cardiovascular Surgical Devices

#### § 870.4075 Endomyocardial biopsy device.

(a) *Identification*. An endomyocardial biopsy device is a device used in a catheterization procedure to remove samples of tissue from the inner wall of the heart.

(b) *Classification*. Class II (performance standards).

#### § 870.4200 Cardiopulmonary bypass accessory equipment.

(a) *Identification*. Cardiopulmonary bypass accessory equipment is a device that has no contact with blood and that is used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system-priming equipment.

(b) *Classification*. (1) Class I. The device is classified as class I if it does not involve an electrical connection to the patient. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 870.9.

(2) Class II (special controls). The device is classified as class II if it involves an electrical connection to the patient. The special controls are as follows:

(i) The performance standard under part 898 of this chapter, and

(ii) The guidance document entitled “Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.” The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 870.9.

[65 FR 19319, Apr. 11, 2000]

## 21 CFR Ch. I (4–1–05 Edition)

#### § 870.4205 Cardiopulmonary bypass bubble detector.

(a) *Identification*. A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit.

(b) *Classification*. Class II (performance standards).

#### § 870.4210 Cardiopulmonary bypass vascular catheter, cannula, or tubing.

(a) *Identification*. A cardiopulmonary bypass vascular catheter, cannula, or tubing is a device used in cardiopulmonary surgery to cannulate the vessels, perfuse the coronary arteries, and to interconnect the catheters and cannulas with an oxygenator. The device includes accessory bypass equipment.

(b) *Classification*. Class II (performance standards).

#### § 870.4220 Cardiopulmonary bypass heart-lung machine console.

(a) *Identification*. A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.

(b) *Classification*. Class II (performance standards).

#### § 870.4230 Cardiopulmonary bypass defoamer.

(a) *Identification*. A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardiopulmonary bypass surgery to remove gas bubbles from the blood.

(b) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document entitled “Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions.”

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 66 FR 18542, Apr. 10, 2001]